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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/361,630 07/27/99 ZUKER C 2307E- 08421

020350 HM12/0615
TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO CA 94111-3834

EXAMINER

WINKLER, U

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

06/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/361,630

Applicant(s)

ZUKER ET AL.

Examiner

Ulrike Winkler, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 37-98 is/are pending in the application.
- 4a) Of the above claim(s) 1-35, 41-45 and 48-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-40, 46, 47 and 94-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

The Amendment filed 6 April 2001 (Paper No. 13) in response to the Office Action of 7 November 2000 is acknowledged and has been entered. Claims 36 has been cancelled. Claims 94-98 have been added. Claims 1-35 and 37-98 are pending, claims 32-40, 46, 47, and 94-98 are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The rejection of claim 36 under 35 U.S.C. 101 is **withdrawn** due to cancellation of the claim. The rejection of claims 32-35, 37-40, 46, 47 and newly added claims 94-98 is **maintained** for reasons of under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Applicant's arguments have been fully considered but are not found to be persuasive. Applicant's main argument is that the utility is that the sequences would be useful as a pharmacological tool. Yet neither the specification as filed nor the art disclose any activity for the protein Tcp2 such that a utility would be well established. At best, the specification merely indicates that Tcp-2 exhibits specific or preferential expression in taste buds (page 55, line 9-11). As such, the protein has not been characterized in regards to its biological function or properties to identify the protein as a receptor, part of the g-protein transduction signal complex or an ion channel. The claims are drawn to using the sequences as hybridization tools under stringent conditions. Since the sequences are not associated with any disease, the hybridization tool would merely serve to indicate that the sequences are expressed in taste buds, which does not define it as a substantial utility.

The rejection of claim 36 under 35 U.S.C. 112, first paragraph is **withdrawn** due to cancellation of the claim. The rejection of claims 32-35, 37-40, 46, 47 and newly added claims 94-98 is **maintained** for reasons of record under 35 U.S.C. 112, first paragraph. Applicant's arguments have been fully considered but are not deemed persuasive. Since there is no specific utility associated with Tcp-2 one of skill in the art would not know how to use the invention without undue experimentation.

The rejection of claim 36 under 35 U.S.C. 112, first paragraph is **withdrawn** due to cancellation of the claim. The rejection of claims 32-35, 37- 40, 46, 47 and newly added claims 95 and 98 is **maintained** for reasons U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's arguments have been fully considered but are not deemed persuasive. Applicant's main point is that according to *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) "a considerable experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed". Applicant asserts that the specification provides a reasonable amount of guidance to meet the criteria of *In re Wands*. The examiner disagrees with that assertion for the following reasons:

The Wands factors are as follows: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

(1) The nature of the invention is directed to isolated proteins that are associated with taste buds. (2) The state of the prior art is such that the biochemical nature of the receptors involved in sensory transduction of chemical stimuli is poorly understood, (3) indicating that the predictability in the art is very low. The taste response is sensitive to salt, bitter, sweet and sour and a combination of mixtures thereof. To date, the information regarding the structural requirements for the bitter-responsive receptors that are coupled to gustducin is poorly understood. For instance, one taste sensation, bitter transduction, can involve disruption of the lipid bilayer, blockage of K channels, direct activation of the G proteins, or activation of G-protein coupled heptahelical receptors (see Ming et al. PNAS 1998, discussion). The sensation of bitter is speculated to be caused by a conformation change in the receptor. (4) The specification provides a detailed prophetic description of the experimental procedures that remain to be investigated. There is no teaching as to the specific role the taste cell proteins play in the taste transduction pathway; all that is taught is that the TCP2 is associated and expressed in taste cells. Based on the specification, it has not been determined that the proteins are involved in the taste transduction at all. These proteins may be structural proteins that serve no specific function in the taste process. (5) There are no working examples provided in the specification that would provide guidance to the ordinary artisan to determine the involvement of TCP in the taste transduction process. (6) The quantity of experimentation necessary to determine if TCP is involved in the taste transduction process is high. Determining if it is involved in the sensation of perceiving bitter, salty, sour or sweet would require extensive experimentation. (7) The relative skill required in the art is high. (8) The claims are broadly drawn to include nucleotide sequences that encode a protein that are at least 70% or greater identity in sequence identity.

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Since the activity of the protein is not known, it would be impossible for one of high skill in the art to determine that a nucleotide sequence that fits the requirements set out in the claims would predictably have the same activity. Therefore, in view of the speculative nature of the invention, the lack of predictability of the prior art, the breadth of the claims and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as claimed, and the rejection is maintained.

The rejection of claim 36 under 35 U.S.C. 112, first paragraph, is **withdrawn** due to cancellation of the claim.

Conclusion

No claims are allowed.

SEQ ID NO: 3, 4, 13, 13, 21 and 22 are apparently free of the prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.


JEFFREY STUCKER
PRIMARY EXAMINER